JUN 2 4 2003

K023955

510(k) SUMMARY

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
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SPARKS, MD 21152
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Contact Name: Colleen A. Kistler
Regulatory Affairs Specialist

Date Prepared: June 23, 2003

Device Trade Name: BD Viper™ Instrument

Device Common Name: Pipetting System for Clinical Use

Device Classification: 21 CFR§862.2750

Predicate Devices: BD ProbeTec™ ET System (K984631)
Impact/Impact 2 (K940390/K961694)
Mini Sample Processor (K970616)

Intended Use:

The BD Viper™ instrument is intended for use as a sample processor designed for use with the BD ProbeTec™ ET system and the BD ProbeTec ET *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) assays. The BD Viper instrument automates the transfer and mixing of manually prepared and lysed samples. The BD Viper instrument incorporates heating blocks to perform assay priming and prewarming incubation steps prior to the removal and transfer of the microwells to the BD ProbeTec ET instrument for amplification and detection.

Device Description:

The BD Viper is a sample processor designed for use with the BD ProbeTec ET system. The BD Viper automates the transfer and mixing of specimens that have been prepared and lysed according to the specific BD ProbeTec ET assay package insert. Automated specimen transfers by the BD Viper occur from the sample processing tubes to the assay priming microwells and from the priming microwells to the assay amplification microwells. The BD Viper also controls the incubation steps for priming the samples and pre-warming the amplification microwells. After the BD Viper transfers samples from the priming wells to the amplification microwells, the instrument mixes the contents of the amplification microwells. After mixing, the plates are manually sealed and removed from the BD Viper. The sealed plates are placed into the BD ProbeTec ET instrument(s) where the analyte specific amplification and detection process occurs.

The BD Viper is comprised of four major components: robotic pipetting arm, priming and warming heaters, LCD monitor with integrated touch screen, and instrument software.

Device Comparison To Other Legally Marketed Predicate Devices:

The primary operational components of the BD Viper are substantially equivalent[1] to other legally marketed devices intended for the automation of pipetting and processing functions associated with laboratory assays. The BD Viper has been compared to the BD ProbeTec ET System utilizing the MATRIX Impact and Impact 2 Pipettor (BD ProbeTec ET Pipettor) and heating blocks, and the CAVRO MSP 9500 Mini Sample Processor.

Although there are technologic differences between the BD Viper and the predicate devices, these differences do not raise any new or significant safety issues. These devices are similar in that they are designed to pipette, transfer, and heat liquid sample volumes associated with the performance of laboratory assays. The effectiveness of the BD Viper is established by comparing and assessing the performance of the BD ProbeTec ET system using the BD Viper (automated method) versus the performance of the BD ProbeTec ET system using the BD ProbeTec ET Pipettor and heating blocks (manual method).

Comparison of the BD Viper to the BD ProbeTec ET Manual Assay

The BD ProbeTec ET system using the BD Viper (automated method) is similar to the BD ProbeTec ET system using the BD ProbeTec ET Pipettor and heating blocks (manual method) in that:

- Both systems incorporate assay specific pipetting steps of equal volumes.
- Both systems utilize negative pressure fluid movement.
- Both systems incorporate the use of heating blocks to incubate microwell assay plates.
- Both systems utilize the same assay specific heating temperatures.
- Both systems utilize the same assay reagents.
- Both systems use specimens that have been manually prepared and lysed according to the specific BD ProbeTec ET assay package insert.
- Both systems comprise the necessary steps for the handling of lysed specimen from sample tube to priming microwells and then to amplification microwells.
- Both systems utilize the BD ProbeTec ET instrument for amplification, detection and reporting of assay results.

The BD ProbeTec ET system using the BD Viper (automated method) differs from the BD ProbeTec ET system using the BD ProbeTec ET Pipettor and heating blocks (manual method) in that:

- BD Viper automates some portions of the BD ProbeTec ET manual assay.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

- BD Viper incorporates the use of thin low mass heat blocks that have the ability to ramp quickly from ambient temperature to the desired assay temperature through the use of software as compared to the BD ProbeTec ET manual assay which incorporates the use of thick heat blocks that are maintained at the desired assay temperature throughout the procedure.

Summary Of Performance Data:
Several analytical instrument studies and a clinical study were designed and conducted in order to verify that the BD ProbeTec ET System using the BD Viper instrument (automated method) performed comparably to the BD ProbeTec ET System using the BD ProbeTec ET Pipettor (manual method).

Contamination Studies
A study was performed to evaluate the potential for contamination associated with automating particular specimen pipetting and processing steps performed by the BD Viper instrument. Specifically, the study was designed to evaluate the risk of producing a false positive result in one assay due to the presence of a positive sample in another assay that was performed on the same instrument, either in the same run (cross-contamination) or in a previous run (carry-over).

Environmental Studies
Studies were conducted to demonstrate that critical parameters of the BD Viper instrument were acceptable when the instrument was operated in a simulated laboratory at specified environmental conditions as stated in the BD Viper Instrument User Manual.

Precision Studies
The precision of the BD Viper instrument was assessed by testing a six member panel consisting of various levels of *C. trachomatis* and *N. gonorrhoeae* organisms in BD ProbeTec ET CT/GC diluent and a negative sample comprised of uninoculated BD ProbeTec ET CT/GC diluent. Six replicates of each panel member were tested once a day for three days on three BD Viper instruments. A variance component analysis was performed to establish overall precision of the BD Viper instrument.

Clinical Percent Agreement
A clinical evaluation was conducted internally and externally at two clinical centers to evaluate the percent agreement of over 4,000 paired CT and GC results between the BD ProbeTec ET automated and manual methods.

Conclusions
The BD Viper™ instrument is intended for use as a sample processor designed for use with the BD ProbeTec™ ET system. The BD Viper instrument automates the transfer and mixing of manually prepared and lysed samples. The BD Viper instrument incorporates heating blocks to perform assay priming and prewarming incubation steps prior to the removal and transfer of the microwells to the BD ProbeTec ET instrument for amplification and detection. The instrument gives substantially equivalent[1] analytical performance to other pipetting devices. Based on the clinical performance data, substantially equivalent[1] results were obtained for the BD ProbeTec ET CT/GC Assay when performed using the BD ProbeTec ET automated and manual methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 24 2003

Ms. Colleen A. Kistler
Regulatory Affairs Specialist
BD Diagnostics Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Re: k023955
Trade/Device Name: BD Viper™ Instrument
Regulation Number: 21 CFR 862.2750
Regulation Name: Pipetting & Diluting System
Regulatory Class: Class I
Product Code: JQW
Dated: May 15, 2003
Received: May 16, 2003

Dear Ms. Kistler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023955

Device Name: BD Viper™ Instrument

Indications for Use:

The BD Viper™ instrument is intended for use as a sample processor designed for use with the BDProbeTec™ ET system and the BD ProbeTec ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* assays. The BD Viper instrument automates the transfer and mixing of manually prepared and lysed samples. The BD Viper instrument incorporates heating blocks to perform assay priming and prewarming incubation steps prior to the removal and transfer of the microwells to the BDProbeTec ET instrument for amplification and detection.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K023955

(Optional Format 3-10-98)